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Understanding involvement in surgical orthopaedic randomized controlled trials: A qualitative study of patient and health professional views and experiences

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KEYWORDS

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Views

Abstract Background: Factors influencing patients' motivations for enrolling in, and their experiences of, orthopaedic randomized controlled trials (RCTs) are not fully understood. Less is known about healthcare professionals' (HCP) experiences of RCT involvement.

Aim: This study investigates patients' and HCPs' views and experiences of RCT participation and delivery to inform the planning of future RCTs.

Methods: Total hip or knee replacement patients (n = 24) participating in the single-center double-blind APEX RCTs of an intra-operative anesthetic intervention and HCPs (n = 15) involved in trial delivery were interviewed. Data were audio-recorded, transcribed, anonymized and thematically analyzed.

Results: Although altruistic reasons for RCT participation were common, patients also weighed up demands of the RCT with the potential benefits of taking part, demonstrating the complex and conditional nature of trial participation. HCPs were interested in RCT involvement as a means of contributing towards advances in medical knowledge and also considered the costs and benefits of RCT involvement.

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Conclusion: Patients and HCPs value involvement in RCTs that they see as relevant and of value, while imposing minimum burden. These findings have important implications for the design of methods to recruit patients to RCTs and for planning how an RCT might best interface with HCP clinical commitments.

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Editor comments

Orthopaedic and trauma practitioners are increasingly involved in research studies. Sometimes they are participants in the research process. They might also be research nurses who are involved in study design, data collection and analysis. As previously discussed in this journal, research is everyone's responsibility and practitioners will often simply meet patients in the course of their everyday work who are participating in a research study and require nursing support. An understanding of how research happens and the impact this has on participants is central to providing good care to patients who are participants in studies. This paper provides some important information about the way patients feel about their involvement. It also provides important insight into the research process and salient ethical issues with particular reference to randomized controlled trials. This gives practitioners a practical view of the conduct of research that can also help them to understand the process better.

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Introduction

Randomized controlled trials (RCTs) are internationally recognized as the gold standard for evidence-based medicine, important for determining the effectiveness of medical interventions and directing medical practice (Brighton et al., 2003; Malavolta et al., 2011). Limitations in the present orthopaedic evidence base include a scarcity of RCTs (Chaudhry et al., 2008), relatively poor quality of orthopaedic RCTs and their reporting standards such that they receive poor rating in meta-analyses (Bhandari et al., 2003). This has led to a growing emphasis on the importance of providing orthopaedic evidence through high quality RCTs (Chaudhry et al., 2008; Swiontkowski and Agel, 2012; Tornetta et al., 2012).

The success of RCTs relies on adequate and timely recruitment. Recent reviews have concluded that recruitment problems are evident in the majority of RCTs (McDonald et al., 2006; Treweek et al., 2010). Less than a third of RCTs achieve their recruitment targets (Fletcher et al., 2012; McDonald et al., 2006), which can undermine the power of an RCT, lead to sampling bias and limit generalizability of results. Patients' motivations for research participation are multifaceted and complex (Hallowell et al., 2010). Common reasons include an altruistic belief that the research will benefit others and a view that a direct benefit will accrue from research participation (McCann et al., 2010). While some patients describe participation based on one or other of these

reasons, the majority of patients report a mix of altruism and self-interest (Carroll et al., 2012; Locock and Smith, 2011; McCann et al., 2010; Sikweyiya and Jewkes, 2013). Potential RCT participants' decision-making involves weighing up perceived benefits and burden of RCT involvement to themselves, alongside the potential wider social contribution of the research (Cox and McGarry, 2003; McCann et al., 2010). The complexity of the decision-making process reveals why recruitment is an ongoing issue in RCTs (McDonald et al., 2006; Treweek et al., 2010).

Retention of patients in RCTs is also of utmost importance since the validity of RCT findings depends on the completeness of follow-up data to ensure an adequate pool of data is available to enable robust analysis. Evidence suggests that effective recruitment leads to the retention of patients (Jerosch-Herold et al., 2011; Poston and Buescher, 2010). Unrealistic expectations of trial requirements, perceived benefits or preference for treatment arms can lead patients to drop out of studies (Abraham et al., 2006; Paramasivan et al., 2011). It is therefore vital, and an ethical obligation, that patients are fully informed of the requirements of RCT participation and have realistic expectations about possible benefits and risks regardless of treatment assignment (Mann et al., 2013), to be able to consider trial participation fully and provide free and informed consent (Donovan et al., 2009). Despite the large number of orthopaedic patients entering RCTs, there is a lack of research examining the factors that influence orthopaedic patients' motivations for, and

experiences of, RCT participation. These can be integral to adequate trial recruitment (Sikweyiya and Jewkes, 2013), leading to effective retention of participants and completion of RCTs within the available time and resources (Jerosch-Herold et al., 2011; Tramm et al., 2013).

Healthcare professionals' (HCPs) engagement with RCT processes is as important as that of patients and can directly influence the quality of RCTs (Rendell et al., 2007). By design, clinical RCTs are conducted within busy clinical environments and often rely on a range of HCPs to assist with RCT recruitment, delivery, care of RCT patients and data collection while continuing with existing clinical commitments. The majority of research investigating the issues pertinent to HCPs' involvement in RCTs has focused on the effect of their views on recruitment to studies (Ellis et al., 2001; Rendell et al., 2007; Siminoff et al., 2000). There is also a paucity of research that has examined the views and experiences of HCPs involved in other aspects of RCT delivery. With a pressing need for more high quality orthopaedic RCTs (Tornetta et al., 2012) it is important to understand the impact of conducting a large scale RCT in an orthopaedic service.

Using qualitative methods, the present study aimed to examine the views and experiences of HCPs delivering orthopaedic RCTs and patients participating in the same RCTs. This aimed to enable the identification of factors that may enhance our understanding of how best to deliver successful orthopaedic RCTs and inform the design and delivery of future RCTs.

Materials and methods

Study design

A qualitative in-depth interview study embedded within the recent single center double-blind APEX (Arthroplasty Pain Experience) RCTs was conducted at a UK high volume orthopaedic center (ISRCTN96095682) (Wylde et al., 2015). Qualitative methods were chosen as the most appropriate means to achieving a nuanced understanding of RCT involvement (Locock and Smith, 2011; McCann et al., 2010). The APEX trials were designed to evaluate the effect of intra-operative local anesthetic wound infiltration on the severity of joint pain at 12-months after primary total knee replacement (TKR) or total hip replacement (THR). Patients awaiting TKR or THR were randomized to one of two groups: i) standard anesthetic care; ii) intra-operative wound infiltration with a local anesthetic in addition to the standard anesthetic care. All patients were assessed

pre-operatively, daily during the hospital stay and then at 3-months, 6-months and 12-months. Outcome measures included self-report questionnaires, joint examinations, analysis of x-rays, pressure algometry and extraction of data from hospital records. The primary outcome was the WOMAC pain subscale (Bellamy et al., 1988) at 12-months. The RCTs successfully recruited 316 TKR and 322 THR patients between November 2009 and February 2012 (Wylde et al., 2015). Four research nurses recruited patients and assisted with data collection while patients were in hospital. During the pilot stage of APEX the recruitment nurses performed peer-review of recruitment interviews to develop communication skills required to convey RCT information to patients (Mann et al., 2013).

Southampton and South West Hampshire NHS Research Ethics Committee (B) (09/H0504/94) provided approval for the APEX trial and embedded interview study.

Procedure

Patients listed for THR or TKR were sent APEX trial information. Patients then attended pre-operative assessment clinics before their surgery, were approached about participation in APEX by a research nurse and were asked if they were willing to be contacted about taking part in an interview. From those who agreed to be contacted about the interview, a purposive sample (in relation to age, gender and balance of operated joint) was selected to gain a diverse sample. HCPs were sampled to include those involved in all stages of APEX: pre-assessment, surgery and post-operative recovery.

All participants provided written, informed consent prior to the in-depth interview. Flexible interview topic guides were used to ensure primary issues were covered during all interviews, but without dictating data collection. This allowed participants to introduce unanticipated issues and in line with an inductive approach these were revised in light of emerging findings. Open-ended questioning techniques were used to elicit participants' experiences and views of key events of joint replacement and trial participation. Patients' accounts of their experiences of joint replacement have been published elsewhere (Johnson et al., 2014). Within the exploration of trial participation, interviews examined participants' initial impressions of the trial; knowledge and expectations of the trial (including aims, trial arms, clinical equipoise, randomization, blinding and data collection); decision-making regarding trial participation and experience and acceptability of the trial (see Box 1). Analyses

Box 1

Interview schedule

- Initial impressions: How did you first hear about the APEX study? First impressions?
- Understanding: Study aims, trial arms, randomization, blinding, equipoise, what taking part would involve, data collection, follow up period.
- Decision making: Why take part?
- Knowledge and expectations: Participation in research, trial arm (active, control), surgery
- Experience of trial participation/involvement: Acceptability, what worked well and improvements
- Data collection: Acceptability, timing
- Information and support: What worked well and improvements

proceeded in parallel to data collection and continued until data saturation was reached such that no new themes were arising from the data (Sandelowski, 1995). Patient interviews were conducted in participants' own homes by EJ between April 2010 and January 2011. HCP interviews were undertaken in a private office on hospital premises by EJ (n = 13) and JH (n = 2) between March 2011 and June 2012.

Data analysis

Interviews were audio-recorded, fully transcribed, anonymized, checked for accuracy and imported into a qualitative software package to aid data analysis. Thematic analysis (Braun and Clarke, 2006) was used to scrutinize the data to identify and analyze patterns across the dataset. Transcripts were examined on a line-by-line basis with codes assigned to segments of the data and an initial coding frame developed. An inductive approach to coding was used to identify participants' perceptions of their experiences. This generated an initial coding framework which was added to and refined as new data were gathered. Codes were gradually built into broader categories through comparison across transcripts and higher-level recurring themes were developed. EJ undertook the initial systematic coding of the transcripts. A subset of 4 patient and 8 HCP transcripts was independently analyzed by JH and RGH and any discrepancies discussed to contribute to the generation and refinement of codes and thematic categories to maximize rigor (Meyrick, 2006).

Results

Twenty six patients were invited to take part in the interview and 24 agreed. These were 11 men and 13 women, aged 26–92 years (mean 65 years), 14 were undergoing THR and 10 were undergoing TKR, 23 were

of white British ethnicity. Interviews lasting between 45 and 120 minutes were conducted two to four weeks after surgery. Fifteen HCPs were approached and all agreed to take part. These were 4 men and 11 women, aged 28–56 years (mean 44 years), comprising 3 pre-operative clinic nursing staff, 4 orthopaedic surgeons and 2 consultant anaesthetists, 4 ward nurses and 2 ward managers. Interviews with HCPs lasted between 19 and 40 minutes.

Analysis led to the development of key themes that relate to views and experiences of the APEX trials. Themes provide information about patients' rationale for taking part, their experiences of participation and HCPs' views and experiences of trial involvement. All initials refer to pseudonyms.

Patients' reasons for RCT participation: benefiting others

Patients said that they wanted to participate in an RCT that had the potential to impact on other patients and to the advancement of knowledge. This 'altruism' was a prominent feature in the majority of the patients' accounts. Patients described the value of the research on future patients in the context of commitment and belief in the value of research. A desire to help future patients was seen as part of a wider system of reciprocal 'social exchange' that included reflection on the past as well as the future: patients expressed gratitude to unknown members of previous generations who had participated in research that had contributed to improvements in medical care that they were currently receiving.

Well I just thought that anything that might help people in the future. You know if people don't do things like that [then] improvements might take place but probably a lot more slowly. I think that it's a good thing to do for the benefit of people who

are having operations in the future really that's why. Mrs B, THR, age 65.

I feel if I can help other people from my experiences then all well and good. That's what it's about so as I say how are they gonna learn if you can't learn from other people. Mr I, TKR, age 51.

My attitude to that [trial involvement] is things they know now somebody has done that in the past so if they learn more it's going to be valuable to people in the future. I'm all for that. . . Years ago they used to cut peoples legs off with saws, they've moved on quite a bit from that haven't they. Mrs Q, THR age 75.

If I can help somebody else because somebody had probably done something before me that could help me. Mrs P, TKR, age 72.

Potential benefits to patients

Although altruistic reasons for RCT participation were common, patients frequently also said that they had considered the possibility that participation might confer physical benefits to them in the shape of additional pain relief. Patients described the potential benefit of receiving more anesthetic if they had been randomized to the intervention arm of APEX while also demonstrating a good understanding of the process of randomization and blinding.

When she [recruitment nurse] said they would inject into the scar before they send me up I thought 'oh lovely a bit more pain, less pain', but I don't know whether I had it done so I suppose it is in my mind. I might have had it I don't know. Mrs P, TKR age 76.

As well as possible physical benefits of RCT participation, patients described a range of potential psychological benefits. Some patients felt they might benefit from the research team monitoring their health, for example: *'somebody else is looking from another corner at me'*. Patients also thought that completion of the questionnaires provided an alternative way to express, and thereby better understand, their pain and outcomes. The daily 100 mm pain visual analogue scale (VAS) pain scores that patients were asked to complete on days 1–3 post-operative while in hospital helped quantify the patients' pain experience and learn more about their recovery from surgery. In addition patients reported a satisfaction and curiosity from contributing to research and were keen to know the results of the RCT, including the arm that they were allocated to, which was information that they would receive after RCT completion.

I think for a certain degree that I had some skepticism to a degree in my own mind that if there is a,

what if it went wrong, somebody else is looking from another corner at me, it may help to decipher why, when, where, what how it went wrong. Mr M, THR age 50.

Oh my pain going down? [comparison of pain scores completed in daily in-patient questionnaire] Yes because you don't think do you. You think everyday 'oh it is the same, oh I wish it would hurry up oh it is still there'. But it wasn't you could tell and like when I get up in the morning and I would go to the toilet, have my wash and come back in and then I would sit and fill it [in-patient questionnaire] and I would think 'oh it is a lot better today'. Mrs P, TKR age 76.

I know I've been told it's an opportunity to know [about allocation within the trial] in a year's time if I'm interested and yes I would be interested. Mrs O, THR age 52.

Yes, I suppose it's [allocation within the trial] something to look forward to as well, to find out yay or nay. If it's no well I don't see that, at this particular moment I am healing quite well and getting going in the right direction. Whether it would have made any difference if I had had it or not I don't know, you know what chemical is it by comparison to normal anesthetic, is it a super duper special, I don't know. So there are a lot of questions that I could ask and would like to ask whether I've had it [the intervention] or not, and what about the person who has had it if I haven't, how is he, or she, you know by comparison to me. Mr M, THR age 50.

Patients' perceived benefits and costs of trial participation

For the majority of patients RCT participation was conditional on considering the perceived costs associated with the trial. Patients considered potential costs and benefits of APEX participation and were motivated to take part if they saw few negative consequences to being randomized to either of the trial arms. They considered that APEX participation conferred minimal risk as patients in either trial arm would receive standard anesthetic care while those in the intervention arm would receive additional treatment. Patients viewed both arms as acceptable and did not feel like they would be 'losing out on anything' if they were randomized to receive standard anesthetic care only. Patients understood that APEX was a phase 3 trial of an anesthetic already routinely administered. This contributed to them viewing trial participation as 'low risk' in comparison to a phase 1 trial of a new drug which some said that they would be reluctant to participate in. Additionally, the majority of patients did not see the data

collection requirements of APEX as burdensome. Rather they viewed the data collection methods and length of follow-up to be clear and acceptable. Many stated that trial participation 'gave them something to do' while recovering from surgery and that they had sufficient time available to complete questionnaires. However, a minority of patients did say they struggled with the length of some of the questionnaires.

I thought well it's not as though it's going to be a new drug what you're testing . . . it's only going to be anesthetic but it's only going to be a trial if it works or it didn't work. I mean it's not as though I'm going to lose anything if it doesn't work. I thought if it does work then I've gained a lot so it's not as though it's going to be a new drug you're trying out. Mrs L, TKR age 46.

I thought well I'm retired, I've got time. It's not as though it's going to be difficult to fit it [questionnaire] in and so you know, I've never thought 'oh why did I do that?' Mrs B, THR age 65.

Yeah, I thought, 'Well, somebody got to do it', I mean, all these things take time, and someone's got to do it, and I thought, 'Well, I don't mind, I won't be doing anything when I come home'. (Laughs). Yeah, it'd be an interest anyway. Mrs E, THR age 79.

It [questionnaire] was hard work because there were so many pages. Mrs B, THR age 65.

Healthcare professionals' views of RCT involvement

HCPs were happy to be involved in an RCT that was understood to be an acceptable intervention and relevant to the patient experience. HCPs saw pain reduction after surgery to be central to their professional practice.

I think it's [APEX trial] really valuable because the more you can help people with pain, you know, it's really - I think that's one thing that the patients are frightened of, isn't it, when they have surgery with anybody? I would be . . . So, you know, the advances in pain relief and making sure they're relatively pain-free, has got to be good. S8, Senior Nurse, female.

That [the aims of the trial] rolls into what we're doing as well, to what you're doing, and everything is just contributing towards trying to keep the patient pain-free for longer, and to get them more mobile, and to get them out back into their own home, which is good. S9, Trainee Nurse Practitioner, female.

I thought that it was a good idea to give a little local anesthetic, you know, so the patient, they're more

comfortable when they wake up and the body gets time to acclimatize, so to speak, to the pain, rather than they wake up in serious pain. S10, Surgeon, male.

Impact of RCT involvement

HCPs considered the potential impact of their involvement in the delivery of APEX. Some did report initial concerns including the possibility that their professional conduct would be under scrutiny, an increase in their workload and the logistics of recruiting patients in a busy clinic. These concerns were alleviated once they learnt more about APEX, with many commenting that they appreciated that it had been designed to have minimal impact on, and to be normalized into, their routine clinical practice.

It was a little bit worrying and we'd think, 'oh gosh, you know, we're all being watched.' (laughs) You know, because you do think, oh research, are people going to be coming in, and are they going to be asking lots of questions? And I suppose sometimes there is a fear there of thinking, 'oh my gosh, you know, what is going to be expected?' S2, Ward Nurse, female.

No I have no problem, I mean it's a great opportunity to contribute to research . . . So there's not much that we have to do there. OK, we had to just do a standardized anesthetic and fill in the form, so I think you didn't ask for too much. S14, Consultant Anesthetist, female.

Well it's just like part of what happens now. S7, Pre-op Clinic Manager, female.

I thought it was going to be OK because essentially it was using the same anesthetic that we were already using for the knee, um for our primary knee replacements. So I didn't think it would have much impact on what I did, in terms of the anesthetic, so I was quite happy to go along with it. S12, Consultant Anesthetist, female.

HCPs noted that the APEX research nurses played a central support role in the smooth running of the RCT. The research nurses were a visual reminder of APEX and their daily presence allowed for opportunities to clarify procedural details and reduce any burden of the RCT on HCPs, which was appreciated and welcomed.

Seeing someone every day is good. You know they [research nurses] are going to come up, if there's any issues. Um. I suppose because I know [Orthopaedic surgeon] quite well that if I had any problems then I could always, you know. He's very approachable. As are all the team so I could easily. So I think that's worked well that they're very visible. S5, Ward Manager, female.

If we're not sure about it [APEX trial], we do ask, you know. We've asked the APEX nurses, you know, if we felt we weren't sure on anything we could still go up and ask them things, and that was really good. S2, Ward Nurse, female.

We haven't really asked for as much help as they [research nurses] have offered. They have been here and given us a lot of information and they have again been offering staff any support they can possibly think of and um you know whether it was to do with filling out the forms or where we put the forms after we have completed them. You know what sort of support we need to give the patients. So yes they've been excellent really. S6, Ward Manager, female.

RCT visibility

An initial challenge for trial conduct was the need to inform a large clinical team (pre-assessment, surgical and ward staff) about the presence of APEX and the requirements it would place on them. HCPs welcomed the diverse methods used initially to notify them about APEX and subsequently about its progress. APEX posters were displayed in hospital corridors and these were thought to be an effective means to inform patients and remind HCPs about APEX. For HCPs, the availability of the APEX protocol in clinical workplaces helped them to implement the APEX trials. Increasing the visibility of protocols as APEX progressed was described as of value. Some ward-based HCPs reflected that receiving information personally would have been more helpful to them than the generic information provided.

Alongside information within the hospital, APEX was publicly launched with a local media presence in newspapers and television. Pre-operative assessment clinic staff, where patients were recruited, commented on the positive impact of the media campaign, with patients more willing to wait longer to speak to the recruiting research nurses.

We were told at our staff meeting, which was really good. . . . By [manager name]. But also the posters around the place as well, you know, informing the patients and, you know, just highlighting it again to the staff. S9, Trainee Nurse Practitioner, female.
I first heard about it from [Surgeon], you know, by just discussing it, you know, and then we had a few talks in the department about it. [Anesthetist], who is on your steering committee and a co-applicant, would send emails around about what is required, so it was quite well advertised. S14, Consultant Anesthetist, female.

We had copies of the protocol in the anesthetic room. I suppose at the beginning the protocols were less obvious. So recently, probably in the last, I don't

know when they were done, but they were laminated and put up and so they were definitely there telling you exactly what to do at each stage. S12, Consultant Anesthetist, female.

I just think sometimes obviously, instead of just saying, 'Oh everything's in a folder', because we've got so many policies and things like that to read, it would be quite nice if we had sort of like a leaflet, you know, a letter that we could open. And I think more people would tend to read over that than be able to make the time to go and see another folder. S2, Ward Nurse, female.

Because there was something, was it on the television or in the newspaper? . . . Yeah and after that happened, more patients asked, which I think it made the whole thing easier. Because patients were asking, we could ask them to wait a bit more . . . Whereas when they didn't know about it they were reluctant to wait. S7, Pre-op Clinic Manager, female.

Discussion

The study sought to investigate patients' and HCPs' views of RCT involvement. Both parties reported they were initially interested in APEX as they saw it as a crucial area of research and of great relevance to patients' experiences of surgery. Findings demonstrate the importance of addressing a question of substantial interest, relevance and value to both HCPs and patients. This demonstrates the need to provide clear information for both patients and HCPs to explain the rationale and significance of an RCT.

Patients were motivated to participate in APEX by a combination of altruism, perceived benefits (or absence of concerns) and consideration of the trial requirements. APEX was seen to present minimum burden: patients saw the possibility of randomization to either trial arms and the requirements of data collection as acceptable. A minority of patients stated purely altruistic reasons for trial participation, with many additionally reporting a variety of potential psychological and physical personal benefits. Perceived benefits included possible reduced pain, active engagement in their health and intellectual curiosity. Concurrently, patients demonstrated sound understanding of the APEX trial design and the processes of randomization and blinding by acknowledging that they may not personally benefit from the RCT. Our findings concur with findings from other patient groups which suggest that individuals are rarely motivated to take part in research based solely on the altruistic consideration of helping others (Carroll et al., 2012; Locock and Smith, 2011; McCann et al., 2010; Simmonds et al., 2013). Rather, individuals

are more likely to be motivated by 'conditional altruism' (McCann et al., 2010) where individuals may additionally perceive some personal benefit (and no significant disadvantage) in taking part in research (Carroll et al., 2012; Locock and Smith, 2011; McCann et al., 2010; Simmonds et al., 2013).

It is therefore important to understand that motivations for trial participation are multifaceted and interrelated (Hallowell et al., 2010; Locock and Smith, 2011) and should be considered in the context of both personal and social benefits (McCann et al., 2010). Mentioning altruism during recruitment as a means of reminding patients of the trial purpose has been advocated (Joffe, 2006) but this needs to be done with an awareness that personal consideration of benefits also plays an important role in RCT participation decisions. Our findings demonstrate the importance of employing a patient-centered approach during recruitment and allowing time to provide clear information about each trial arm and the requirements that participation entails, as previously suggested (Morris and Bälmer, 2006). This should be done alongside exposure and discussion of any misunderstandings about the RCT as well as addressing expectations that might not be met (Sikweyiya and Jewkes, 2013; Wasan et al., 2009). Peer-review has already been used to assist recruitment staff to develop their communication skills (Mann et al., 2013) and can ensure recruitment interviews are personalized, rather than an 'one size fits all' scripted recruitment method.

HCPs also weighed up the perceived benefits and costs associated with APEX involvement. Satisfactory trial burden was accomplished by employing research nurses so APEX had minimal impact on HCPs' daily clinical practice. Research nurses were also valuable for clarifying procedural details to ensure protocol adherence. Our study demonstrates that RCTs have the potential to be successfully normalized into clinical practice. The data reveal the need for minimal personal burden of RCT involvement for all involved. This has been previously suggested as an important factor in increasing satisfaction with trial personnel and trial procedures which can have a positive impact on retention rates (Jerosch-Herold et al., 2011). It is therefore vital that RCTs are carefully planned and adequately resourced to avoid making unnecessary demands which have previously been demonstrated to affect the recruitment of both patients and HCPs (Ellis, 2000; Mason et al., 2007). It is also critical to ensure that data collection requirements and follow-up duration are clinically meaningful and appropriate without placing onerous burden on patients and HCPs to overcome the operational challenges of conducting RCTs in orthopaedic surgery (Losina et al., 2012).

Factors that influence the validity and generalizability of results from RCTs include non-adherence to the study protocol and completeness of follow-up data (Overall et al., 1998). Adherence to protocol is critical to ensure that the outcome of the RCT is attributed to the corresponding treatment arm. RCTs are often conducted in busy clinical environments, over long periods of time and with RCT patients interspersed between routine patients (Swiontkowski and Agel, 2012). It is therefore easy for HCPs to lose focus on RCTs taking place in their clinics. Our data highlight the importance of initial and ongoing visibility of the RCT. The findings from our study indicate that HCPs value the opportunity to discuss the study and its protocol with research staff and that this complements written material. This can be bolstered by ongoing availability of research staff as an RCT progresses. Ensuring completeness of follow-up data when data are patient-reported may hinge on patients' belief in the value of the data and of their participation (Jerosch-Herold et al., 2011; Swiontkowski and Agel, 2012). In the APEX trials patients described the value of trial participation to themselves, to others and to society as a whole. Patients also saw questionnaire completion as potentially beneficial to them and only some found the questionnaire length a challenge. A consideration for future orthopaedic RCTs might be the fact that completion of questionnaires may be seen as beneficial in its own right.

This study aimed to undertake an in-depth investigation of orthopaedic trial participation. The data analysis was robust as a proportion of interview transcripts were coded independently and themes discussed within the research team. A diverse range of patients in terms of age and gender and HCPs in terms of role were interviewed and analysis showed commonality in views and experiences. This has enabled a comprehensive insight into RCT involvement from multiple perspectives and findings may be applicable to other RCTs. However, the data were derived only from patients who agreed to participate in APEX who may hold particular views about research that are not generalizable to the wider population. In addition, the sample was drawn from a single site RCT and most patients were of white British ethnicity, so it is possible that the views and experiences of patients from other locations or of different ethnicities would differ. However, the APEX trial was conducted at one of the largest orthopaedic centers in the UK which serves patients from a wide geographical area.

The study demonstrates that patients and HCPs value contributing to an RCT viewed as relevant and of value. When patients decide to take part in an RCT they also weigh up perceived benefits and demands

of participation alongside altruistic considerations, although altruism is often not the primary motivating factor. It is therefore important to design and adequately resource RCTs so that they impose minimum burden on patients and HCPs.

Conflict of interest statement

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